C. 510(k) Summary

JAN 3 0 2002

Submitter: Dow Pharmaceutical Sciences
1330A Redwood Way
Petaluma, CA 94954
(707) 793-2600

On Behalf of:
Epitest Ltd Oy
Rannankoukku 22
FIN-04300 Tuusula, Finland

Contact: Clawson Bowman, J.D.
Vice President, Regulatory and Clinical Affairs

Date: November 15, 2001

Device Name: Finn Chamber®

Classification Name: Allergen and Vaccine Delivery System

Predicate Device: IQ Chamber (K992553) (Dormer Laboratories, Inc.)

Description:

Finn Chamber® is an aluminum holding device to place allergens and allergen mixes in contact with the surface of skin during allergen patch testing.

This product is intended for use by or under the supervision of a physician in the testing of individuals suspected of having allergies. It is not intended for over-the-counter use. Finn Chamber® is substantially equivalent to various marketed allergen and vaccine delivery systems including IQ Chamber (K992553).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2002

Epitest Limited Oy
C/O Mr. Clawson Bowman
Vice President, Regulatory and Clinical Affairs
Dow Pharmaceutical Sciences
1330A Redwood Way
Petaluma, California 94954-1169

Re: K013820
Trade/Device Name: Finn Chamber ®
Regulation Number: None
Regulation Name: Allergen and Vaccine Delivery System
Regulatory Class: Unclassified
Product Code: LDH
Dated: November 15, 2001
Received: November 16, 2001

Dear Mr. Bowman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013820

B. Statement of Indication for Use

Applicant: Epitest Ltd Oy

510(k) Number: ~~not known~~ K013820

Device Name: Finn Chamber®

Indication For Use:

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This product is intended for use by or under the supervision of a physician in the testing of individuals suspected of having allergies. It is not intended for over-the-counter use.

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K013820